REMARKS

Introduction

Claims 1-17 are pending in this application. With this Amendment, Applicant has amended claims 1-11, and 13-17. Upon entry of the above amendments, claims 1-17 will be pending in this application.

Claim Rejections

Rejections under 35 USC § 103

35 U.S.C. §103

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. Section 103(a); see Graham v. John Deere Co., 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). "The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." In re Dembiczak, 50 USPQ2d 1614, 1616 (Fed. Cir. 1999).

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Finally, the Examiner must provide whatever additional findings based on the Graham factual inquiries may be necessary. M.P.E.P. §2143. Moreover, to establish a *prima facie* case of obviousness, the Examiner must also demonstrate that there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. See *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007). Even if each feature of a claim can be independently shown within the cited art references, this alone is insufficient to conclude that a claim is obvious in view of such art. *Id.* Instead, to render a claim obvious over a combination of cited references, an Examiner must provide "some articulated reasoning with some rationale underpinning to support the legal conclusion of

obviousness." *Id.* In addition, establishing that a claimed combination is not a "predictable use of prior art elements according to their established functions" may be used to demonstrate nonobviousness. *Id.* at 13. In other words, the Examiner must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 15. Moreover, the Examiner must make "explicit" this rationale of "the apparent reason to combine the known elements in the fashion claimed," including a detailed explanation of "the effects of demands known to the design community or present in the marketplace" and "the background knowledge possessed by a person having ordinary skill in the art." *Id.* at 14. Finally, the Examiner cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention to support an obvious rejection; rather, the Examiner has the burden to show some apparent reason or justification to combine the known elements in the fashion claimed by the patent at issue. *See Id.* and *Smith-Kline Diagnostics, Inc. v. Helena Laboratories Corp.*, 8 U.S.P.Q.2d 1468, 1475 (Fed. Cir.1988).

Claims 1-3, 8-10 and 16

Claims 1-3, 8-10 and 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baldwin, System makes it easier to link patients to clinical trials(hereinafter Baldwin) in view of Angiogenesis Weekly, Clinical Trials: Comprehensive Online Resource Launched (hereinafter Veritas)

Baldwin describes an internet technology applied to a clinical trails database. A database serves 340 physicians whose practices are administered by American Oncology Resources, a practice management firm. The database includes active clinical trials in which AOR is participating. The database is planned to expand to include community cancer trials sponsored by the National Cancer Institute and its cooperative research groups. Patient information is entered online and the profile is compared against a database of ongoing trials. The AOR system is a secure extranet that is only open to select users. Clinicians, drug companies and administrators have varying degrees of access based on a password.

Veritas describes an online medical database which includes 1200 trials. The database can be accessed at the company's website. Patients and physicians are matched against the database of trials. Patients and physicians gain relevant information based on personal needs and attributes, such as phase of disease, age, and gender, without revealing their identity. In particular, patients with HIV and hepatitis come to the site for practical, reliable information about treatment options for chronic conditions. Thousands of visitors can access innovative treatment and trial opportunities.

Neither of these references either taken alone or in combination describe or render obvious Applicant's invention of claim 1. In particular, claim 1 recites a system for finding patients suitable for enrolling in a clinical study from a plurality of hospitals, the system comprising a plurality of hospital database components each being maintained by a corresponding one of the plurality of hospitals and each being operative to maintain a hospital database and its corresponding plurality of patients and medical records and a clinical studies database and its corresponding plurality of clinical studies, a plurality of communications components each being associated with a corresponding one of the plurality of hospital database components, to alert said hospitals to said clinical studies and receive changes to said hospital database components, a plurality of processors each being associated with a corresponding one of the plurality of hospital database components and being programmed to: update said hospital database component, periodically match compatible hospital patients and clinical studies, and generate reports to matched medical practices in said clinical studies, and a coordinator, including a coordinator database to maintain a clinical studies database component and a clinical patient database including non-identifiable information about the plurality of patients, the coordinator including a coordinator communications component, to communicate with each of the plurality of hospital communications components.

None of the references above describes or even suggests such components. In the case of Baldwin and Veritas, both describe databases accessible through the internet, but neither one describes or even suggests the distributed database as claimed by Applicant. There is no description, teaching, or suggestion of Applicant's claimed system including a system having a plurality of hospital database components each being maintained by a corresponding one of the plurality of hospitals and each being operative to maintain a hospital database and its corresponding plurality of patients and medical records and a clinical studies database and its corresponding plurality of clinical studies. In addition, there is no description, teaching or suggestion of a coordinator, including a coordinator database component to maintain a clinical studies database and a clinical patient database including non-identifiable information about the plurality of patients, the coordinator including a coordinator communications component, to communicate with each of the plurality of hospital communications components.

For instance, Baldwin does not describe a database component operative to maintain a medical practice as stated by the Examiner in the Office Action when referring to paragraph 5 of Baldwin. Baldwin merely states that a database of clinical trials is accessible by 340 physicians whose practice is administered by a practice management firm. Baldwin does not

describe a plurality of hospital database components, but merely a database of ongoing trials. Patient information is entered online and compared against the database of ongoing trials. Baldwin only describes a database of ongoing trials which can be searched by an interested physician.

Veritas, likewise, describes nothing more than a database which is accessed by interested individuals, be they physicians or patients. The database is maintained at a company website and includes 1200 trials and relevant information about treatment options. A security architecture enables patients and physicians to access relevant information about relevant trials. While the Examiner states that Veritas teaches matching medical specialties or medical practices (i.e. physicians) with compatible medical studies, Applicant disagrees. Applicant does not find in Veritas a teaching or even a suggestion of medical practices as claimed by the Applicant. Veritas only teaches "patients" and "physicians" in paragraphs 3 and 4, and does not teach or suggest medical practices. Consequently, like Baldwin, only physicians or patients who are motivated to access the trials database would search the database.

Consequently, Applicant believes that claim 1 is allowable. In addition, Applicant believes that claims 2 and 3 which depend from claim 1 contain additional limitations that define over the cited art. Furthermore, since claim 1 is believed to be allowable, claims 2 and 3 are believed to be allowable as well.

Claim 8 has been rejected as being unpatentable over Baldwin in view of Veritas. Claim 8 recites a computerized method for matching patients to clinical studies including identifying at least one hospital from a plurality of hospitals, each of the hospitals having a hospital database component to maintain a hospital database and its corresponding plurality of patients and medical records, identifying at least one clinical study from a plurality of clinical studies, maintaining a coordinator database at a coordinator identifying each of said plurality of hospitals and each of said plurality of clinical studies, and comparing said one hospital and its hospital database to said one clinical study and matching one to the other.

Neither Baldwin nor Veritas taken alone or in combination suggest or teach Applicant's claimed invention of claim 8. Baldwin merely states that a database of clinical trials is accessible by 340 physicians whose practice is administered by a practice management firm. Veritas, likewise, describes nothing more than a database which is accessed by interested individuals, be they physicians or patients.

Consequently, Applicant believes that claim 8 is allowable. In addition, Applicant believes that claims 10 and 16 which depend from claim 8 contain additional limitations that

define over the cited art. Furthermore, since claim 8 is believed to be allowable, claims 10 and 16 are believed to be allowable as well.

For at least these reasons, removal of the rejections and allowance of claims 1-3, 8, 10 and 16 are respectfully requested. If the Examiner should disagree with the Applicant's arguments, the Examiner is asked to kindly point out with particularity where Applicant's claimed invention is disclosed.

Claim 15

Claim 15 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Baldwin, in view of Veritas, Eichenwald et al. and further in view of Knight (U.S. Patent Application No. 2002/0099570).

The Applicant respectfully disagrees with the Examiner's statement that Baldwin discloses "posting a for listing for each said medical study in said clinical studies database (see paragraph 24)." (Office Action, page 6, first full paragraph) Paragraph 24 states only that the system includes all active clinical trials. Applicant does not believe that this paragraph either suggests or teaches posting at least one clinical study on a network accessible computer for review by prospective medical practices and prospective hospitals. Baldwin merely states that a database of clinical trials is accessible by 340 physicians whose practice is administered by a practice management firm. Applicant believes that this paragraph indicates that the trials are included in the database, but not that such trials are posted for review by prospective medical practices and by prospective hospitals.

Likewise, Knight does not suggest or teach Applicant's claimed invention of claim 15. Knight describes techniques for recruiting a patient into a clinical trial. A system for recruiting a patient includes a patient interface, a set of patient specific data, collected from the patient through the patient interface, a set of trial specific criteria corresponding to the clinical trial, a content interface, a set of disease specific data, and instructions for matching, including instructions for coupling the set of patient specific data to disease specific data. Knight, however, does not describe Applicant's claimed invention which includes a computerized method for matching patients to clinical studies including identifying at least one hospital each of the hospitals having a hospital database component to maintain a hospital database, identifying a clinical study, maintaining a database identifying the hospitals and the clinical studies, and comparing the hospital database to a clinical study for matching. Consequently, there is no teaching or suggestion of Applicant's claimed invention.

Consequently, Applicant believes that claim 15 is allowable. In addition, Applicant

believes that claims 15 which depends from claim 8 contains additional limitations that define over the cited art.

Claims 4-6 and 11-14

Claims 4-6 and 11-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Baldwin, in view of Veritas, Eichenwald et al. and further in view of Kraftson et al. (U.S. Patent No. 6,151,581).

Kraftson et al. describes a system and method of building and administrating a patient management hand health management dataset containing data relevant to the clinical care of patient, to the management of the practices to which the patients belong, and to the outcomes of the health care and practice management. A practice enrolling in a system provides information about the practice including costs of care delivery. ('581, column 10, lines 46-50) Applicant does not believe however that Kraftson teaches or describes Applicant's claimed invention of claim 4 including "each of said hospital database components operative to operative to maintain a fee database component" and "each of said processors programmed to calculate a fee total to be paid to each said medical practice and each said hospital." Consequently, there is no teaching or suggestion of Applicant's claimed invention.

In addition, since claim 1 is believed to be allowable, claim 4 is also believed to be allowable. Removal of the rejections and allowance of claims 4 is respectfully requested.

With regard to claim 5, Applicant does not believe that Kraftson et al. teaches or suggests a fee database component identifying fees associated with doctor's procedures and an ancillary fee database component identifying fees associated with miscellaneous charges associated with clinical studies. Consequently, there is no teaching or suggestion of Applicant's claimed invention of claim 5.

In addition, since claim 1 is believed to be allowable, claim 5 is also believed to be allowable. Removal of the rejections and allowance of claims 5 is respectfully requested.

With regard to claim 6, Applicant does not believe that Kraftson et al. teaches or suggests processors programmed to generate a billing statement based upon the total fee and a number of patients actually enrolled. Consequently, there is no teaching or suggestion of Applicant's claimed invention of claim 6.

In addition, since claim 1 is believed to be allowable, claim 6 is also believed to be allowable. Removal of the rejections and allowance of claim 6 is respectfully requested.

With regard to claims 11-14, each of these claims depends from a claim believed to be allowable, therefore claims 11-14 are believed to be allowable as well. Removal of the

rejections and allowance of claims 11-14 is respectfully requested.

Claims 7 and 17

     Claims 7 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Baldwin, in view of Veritas, and further in view of Briegs et al. (US 7,054,823)

     Briegs et al. describes a system for designing and monitoring clinical trials including a main database of information including prior clinical trials and resources to conduct future clinical trials. As stated above, Applicant believes that the limitations of claims 2 and 9 (from which claims 7 and 17 respectively depend) are not shown by the combination of Baldwin and Veritas. In addition, Applicants do not agree with the Examiner's characterization of Briegs wherein the Examiner states that Briegs "discloses a system and method wherein timelines and deadlines for study milestones are generated." (Office Action, page 8, first full paragraph) While Briegs does discuss milestones, Applicant does not find any discussion of "timelines and deadlines" as stated by the Examiner. Applicant believes that Breigs discloses nothing more than a list of tasks. Applicant requests that the Examiner point to specific locations of disclosure in Briegs where "timelines and deadlines" are discussed. Consequently, Applicants believe that there is no teaching or suggestion of Applicant's claimed invention of claim 7 and 17.

     In addition, since claim 1 is believed to be allowable, claim 7 is also believed to be allowable. Since claim 8 is believed to be allowable, claim 17 is believed to be allowable. Removal of the rejections and allowance of claims 7 and 17 is respectfully requested.
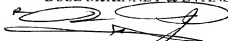
Final Remarks

     Claims 1-17 are believed to be in condition for allowance. Such allowance is respectfully requested.

     If necessary, Applicant requests that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicant requests that any required fees needed beyond those submitted with this Response be charged to the account of Bose McKinney & Evans LLP, Deposit Account Number 02-3223.

Respectfully submitted,

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